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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/905,709 | 08/05/1997 | DAVID STERN | 52876/JPW/JM | 5754 |

7590 05/07/2003

COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

LI, RUIXIANG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1646

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/905,709

Applicant(s)

STERN ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2002 and 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-10, 12, 13, 15-27, 29, 30, 32-39 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 12, 13, 15-27, 29, 30, 32-39 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Application

The Request filed on March 24, 2003 for Continued Examination (RCE) under 37 CFR 1.114 of Application 08/905,709 is granted. An action on the RCE follows.

Applicants' Amendment

Applicants' amendment in Paper No. 25 filed on August 29, 2002 has been entered in full. Claims 6, 7, and 40-45 have been canceled. Claim 1 has been amended. Applicants' amendment in Paper No. 31 filed on March 24, 2003 has also been entered in full. On entering these amendments, claims 1-5, 8-10, 12, 13, 15-27, 29, 30, 32-39, and 46 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Rejections

The objection of claims 1-9, 15-18, and 36-37, as set forth at page 3 in the previous Office Action (Paper No. 24), has been withdrawn in view of applicants' amendment to claim 1 and cancellation of claims 6 and 7.

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The rejection of claims 1-10, 12, 13, 15-18, 36-39, and 46 under 35 U.S.C. §112, 1st paragraph, as set forth at pages 3-4 in the previous Office Action (Paper No. 24), has been withdrawn in view of applicants' amendment to the claims and cancellation of claims 6 and 7.

The rejection of claim 6 under 35 U.S.C. § 112, 2nd paragraph, as set forth at page 4 in the previous Office Action (Paper No. 24), has been withdrawn in view of applicants' cancellation of the claim.

The rejection of claims 6 and 7 under 35 U.S.C. § 102 (e), as set forth at pages 5-7 in the previous Office Action (Paper No. 24), has been withdrawn in view of applicants' cancellation of the claims.

Priority

The Examiner has determined that the subject matter defined in claims 1-5, 8-10, 12, 13, 15-27, 29, 30, 32-39, and 46 has an effective filing date of August 5, 1997, which is the filing date of the Application 08/905,709. Application 08/592,070 (filed on January 26, 1996) and 08/755,235 (filed on November 22, 1996) fail to provide adequate support under 35 USC §112 for the instantly claimed invention for the reasons set forth in Paper No. 21 & 24.

Applicants argue that applications 08/592,070 and 08/755,235 provide adequate support under 35 USC §112 for the claims of the present invention, i.e., a method of

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inhibiting atherosclerosis in a subject suffering from hyperlipidemia by administering a polypeptide comprising the V-domain of sRAGE or a derivative thereof. This has been fully considered but is not deemed to be persuasive because the parent applications do not contemplate, (i) a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia by ***administering a polypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiting the interaction between AGE and RAGE***; and (ii) ***a method to inhibit progression of a macrovessel disease in a subject, which comprises administering to the subject a the V-domain of sRAGE or a derivative thereof capable of inhibiting the interaction between AGE and RAGE***.

Application 08/592,070 discloses a method for inhibiting interaction of an amyloid- β peptide with a receptor for advanced glycation end product (RAGE) on the surface of a cell which comprises contacting the cell with an agent capable of inhibiting interaction of the amyloid- β peptide with the RAGE (top of page 11) and a method for treating a subject with a condition (hyperlipidemic atherosclerosis is included in a list) associated with interaction of an amyloid- β peptide with an RAGE on a cell, which comprises administering to the subject an agent capable of inhibiting interaction of the amyloid- β peptide with the RAGE (bottom of page 13). Application 08/592,070 also discloses that RAGE, which binds an amyloid- β peptide, is an immunoglobulin superfamily member and serves as a receptor for both amphotericin (a group I DNA binding protein involved in neuritic outgrowth) and advanced glycation end products (AGEs) (top of page 23).

However, Application 08/592,070 fails to contemplate the invention claimed in Application 08/905,709. *"Administering to the subject an agent capable of inhibiting interaction of the amyloid- β peptide with the RAGE"* is entirely different from *"administering a polypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiting the interaction between AGE and RAGE"*. Application 08/592,070 fails to contemplate the term "V-domain of sRAGE" and "capable of inhibiting the interaction between AGE and RAGE", in spite of the fact that it discloses the use of soluble RAGE as the agent in the method (bottom of page 11) and the RAGE NH₂-terminal sequence (Table 1, page 29). It is also noted that the term "V-domain of sRAGE" only appears in Application 08/905, 709". In addition Application 08/592,070 does not disclose the use of a polypeptide comprising the V-domain of sRAGE in inhibiting progression of a macrovessel disease in a subject. Therefore, the two prior applications fail to contemplate and enable the claimed invention.

Should Applicants disagree with the examiner's factual determination above, it is incumbent upon the applicants to provide the serial number and specific page number(s) of the parent applications filed prior to August 5, 1997, which specifically support the claimed subject matter defined in the instant application for each pending claim.

Claim Rejections Under 35 U. S. C. § 112, 2nd Paragraph

Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claims 38 and 39 are indefinite because they recite the limitation "the agent". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections Under 35 U. S. C. § 102(e)

The rejection of claims 1-5, 8-10, 12, 13, 15-27, 29, 30, 32-39, and 46 under 35 U.S.C. § 102 (e), as set forth at pages 5-7 in the previous Office Action (Paper No. 21 & 24), remains.

Applicants argue (i) that the MPEP states that a rejection based on 35 U.S.C. § 102 (e) can be overcome by perfecting priority under 35 U.S.C. § 120 by amending the specification of the application to contain a specific reference to a prior application and (ii) that the claimed invention is entitled to a priority date of January 26, 1996. This has been fully considered but is not deemed to be persuasive because application 08/592,070, filed on January 26, 1996, fails to contemplate and enable the instantly claimed invention as a whole, as noted above.

Claim Objection

Claims 10, 13, 27, and 30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim (claim 1). Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since the polypeptide recited in claim 1 already comprises the V-domain of sRAGE, requiring it

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... further comprises a portion of sRAGE (claims 10 and 27) or from 3 to 20 amino acids of sRAGE (13 and 30) fails to further claim 1.

Claims 1 and 19 are objected because they recite the terms "sRAGE", "AGE", and "RAGE", which should be spelled out in each independent claim for clarity.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the

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Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
April 25, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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